



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

T 1755 M

Food & Drug Administration
Olympic Towers, Suite 100
300 Pearl Street
Buffalo, NY 14202

April 28, 1998

WARNING LETTER BUF 98-7

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

George L. Zemak, Owner
Zemak Farms
7634 Eagle Valley Road
Savona, New York 14879

Dear Mr. Zemak:

A tissue residue report from the United States Department of Agriculture (USDA), an inspection of your dairy operation, and related investigations by Food and Drug Administration investigators, revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act).

A food is adulterated within the meaning of Section 402(a)(2)(D) of the Act if it contains a new animal drug which is unsafe within the meaning of Section 512 of the Act. On or about October 27, 1997, you offered a cow, identified by USDA laboratory report number [REDACTED] metal ear tag number [REDACTED], and back tag number [REDACTED] for slaughter for human food. USDA analysis of the tissue from this animal revealed the presence of sulfadimethoxine at a level of [REDACTED] ppm in liver tissue and [REDACTED] ppm in muscle tissue. This exceeds the .10 ppm tolerance for sulfadimethoxine in cattle and causes the food to be adulterated. It should be noted that USDA has reported [REDACTED] sulfadimethoxine residues from your farm since 1995, [REDACTED] within the last year.

A food is also adulterated within the meaning of Section 402(a)(4) of the Act if it has been held under conditions whereby it may have been rendered injurious to health. You hold medicated animals bearing potentially harmful drug residues under conditions which are likely to allow them to enter the food supply. For example, you fail to maintain permanent and complete treatment records, and a system to review such records prior to offering medicated cattle for slaughter for human food, to assure an appropriate withdrawal period has been observed to permit depletion of potentially harmful residues of drugs from edible tissues.

You are also adulterating the drug [REDACTED] brand of sulfadimethoxine within the meaning of Section 501(a)(5) of the Act when you fail to maintain adequate medication records to show the drug is used in accordance with its approved labeling.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring your overall operation and the foods you distribute are in compliance with the law.

Mr. George L. Zemak

April 28, 1998

Page 2

Please note it is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for violations of the Act. The fact you caused, or participated in causing, the adulteration of an animal offered for sale through a livestock auction which subsequently sells to an interstate slaughterhouse, is sufficient to hold you responsible for violations of the Act.

You should take prompt action to correct these and all violations existing at your farm, and set up procedures whereby such violations will not recur. Failure to take such action may result in regulatory action, such as injunction, without further notice.

Please notify this office in writing, within 15 days, of the specific steps you have taken to bring your firm into compliance with the law. Your response should include steps taken, or to be taken, to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and time frame within which corrections will be completed. Please include copies of any available documentation demonstrating corrections have been made. Your response may be directed to:

Joseph H. Erdmann, Supervisory Investigator
U.S. Food and Drug Administration
P.O. Box 7197
Syracuse, New York 13261-7197.

Sincerely,



Brenda J. Holman
District Director

abo